

2946168
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 21 1995

1. **SUBMITTER'S NAME:** IVAC CORPORATION
10300 Campus Point Drive
San Diego, CA 92121-1579
(619) 458-7825

CONTACT PERSON: Jennifer S. Hankard
Regulatory Affairs Specialist

DATE PREPARED: December 15, 1994
2. **DEVICE NAME:** Proprietary Name: 1) IVAC Enteral Admin. Sets
2) IVAC Infusion Pumps

Common Names: 1) Enteral Admin. Set
2) Infusion Pump

Classification Names: 1) Gastrointestinal Tube and accessories
2) Infusion Pump
3. **PREDICATE DEVICE:** IVAC 72 Series Enteral Administration Sets and Model 7100 Infusion Pump
4. **DEVICE DESCRIPTION:** The IVAC enteral administration sets (Series 28XXX, 28XX6, 52XXX, 52XX6, 59XXX, 59XX6) incorporate standard IVAC set components and materials. The sets include an enteral adapter and, with some configurations, a pre-attached bag which holds the enteral formula during delivery. The enteral adapter is incompatible with standard ANSI IV set luers which prevents the user from accidentally attaching the enteral adapter to an intravenous set. The infusion pumps regulate fluid flow at the desired rate.
5. **INTENDED USE:** The intended use for the IVAC enteral administration sets is to provide nutrition to patients who have an impaired ability to orally ingest their food. The pumping segment or cassette of the enteral administration set interacts with the pumping mechanism of the infusion pump to regulate fluid flow at the desired rate.
6. **TECHNOLOGICAL CHARACTERISTICS:** The IVAC enteral administration sets (Series 28XXX, 28XX6, 52XXX, 52XX6, 59XXX, 59XX6) and the IVAC 72XXX and 72XX6 enteral sets use the same method of manufacture, incorporate standard set

(continued)

6. **TECHNOLOGICAL
CHARACTERISTICS:**

components, and use standard materials. The primary function of the enteral administration sets are the same. The IVAC infusion pumps (MedSystem, 560, 570, 590, 599) and the IVAC 7100 infusion pump use the same method of manufacture, and incorporate similar components. The primary function of the infusion pumps are the same. The technological characteristics of the devices are the same and raise no new questions of safety and effectiveness. IVAC Corporation concludes that the 28, 52, and 59 series enteral sets and the related infusion pumps are substantially equivalent to the legally marketed IVAC 72 series enteral set and 7100 infusion pump.